510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:

k042927

B. Purpose for Submission:

Clearance of a new VACUETTE evacuated blood collection system

C. Measurand:

Blood plasma

D. Type of Test:

Molecular diagnostic tests

E. Applicant:

Sienna Partners, L.L.C., representative of Greiner BioOne North America

F. Proprietary and Established Names:

Vacuette® EDTA K3 Tubes

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1675

2. Classification:

   II

3. Product code:

   JKA

4. Panel:

   75 Chemistry

H. Intended Use:

1. Intended use(s):

   "VACUETTE® Tubes, Holders and Needles are used together as a system for the collection of venous blood.. VACUETTE® EDTA K3 Tubes are used for testing plasma in molecular diagnostics. The performance characteristics of this device have not been established for molecular diagnostics assays in general. Users must validate use of product for their specific molecular diagnostic assay."

2. Indication(s) for use:

   See intended use above

3. Special conditions for use statement(s):

   For professional use only

4. Special instrument requirements:

   General laboratory equipment

I. Device Description:

The Greiner **VACUETTE®** EDTA K3 tube (containing tri-potassium EDTA) provides a means for collection, processing and transportation of an undiluted plasma specimen in a closed evacuated system. The tube contains spray-dried EDTA, yielding a ratio of 1.8mg/mL of blood when the evacuated tube is filled correctly to its fill volume. The **VACUETTE®** EDTA K3 Tube was FDA cleared on 9/5/96 for general plasma collection under K960860, on 2/26/03 for immunohematology under BK030001, and on 7/28/04 for viral marker testing under BK040018. The matching Greiner tube containing K_2 EDTA (containing di-potassium EDTA) was cleared for molecular diagnostic testing (PCR) on 2/01/02 under k014104.

The **VACUETTE®** EDTA K3 Tube is used for plasma preparation and is made of plastic for the collection of venous blood which upon centrifugation separates undiluted plasma for use in molecular diagnostic test methods or other procedures where an undiluted plasma specimen is required as determined by the laboratory. The tube is composed of clear plastic. The cap is made of plastic and rubber. The product is provided in five fill volumes sizes of 2 mL, 3 mL, 4 mL, 6 mL, and 9 mL and in a non-ridged or ridged format.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Becton Dickinson Vacutainer® Brand PPT™ Plasma Preparation Tube and Glass K_3 EDTA Tube (pre-amendment).

2. Predicate 510(k) number(s):

k972075

3. Comparison with predicate:

	VACUETTE® EDTA K3 Tube	Vacutainer® Brand PPT™ Plasma Preparation Tube	Vacutainer® Brand Glass K_3 EDTA Tube
Intended Use	VACUETTE® Tubes, Holders and Needles are used together as a system for the collection of venous blood. VACUETTE® tubes are used to collect, transport and process blood for testing serum, plasma or whole blood in the clinical laboratory. VACUETTE® EDTA K3 Tubes are used for testing plasma in molecular diagnostics.	To separate undiluted plasma for use in molecular diagnostic test methods including but not limited to PCR (Polymerase Chain Reaction) and bDNA (branched DNA). The specimen may also be used for other testing that requires an undiluted plasma samples as determined by the laboratory	BD Vacutainer® Tubes, Needles and Holders are used together as a system for the collection of venous blood. BD Vacutainer® Tubes are used to transport and process blood for testing serum, plasma or whole blood in the clinical laboratory. (pre-amendment)
Tube Material	Clear Plastic	Clear Plastic	Clear Glass
Additive	K_3 EDTA	EDTA and gel barrier material	K_3 EDTA
Processing Agent	Centrifuge	Centrifuge	Centrifuge

The claim of substantial equivalence to the predicate device Vacutainer® Brand PPT™ Plasma Preparation Tube and Vacutainer® Brand Glass K_3 EDTA Tube is made. VACUETTE® K3 contains the combined features of clear plastic tube and K_3 EDTA as anticoagulant.

K. Standard/Guidance Document Referenced (if applicable):

Not applicable

L. Test Principle:

VACUETTE® K3 tubes are plastic tubes with a pre-defined vacuum for exact draw volumes. They are fitted with color-coded VACUETTE® SAFETY Caps. The tubes, additive concentrations, and their permitted tolerances, as well as the blood-to-additive ratio, are in accordance to the requirements and recommendations of the international standards ISO 6710 "Single-use containers for venous blood specimen collection" and the Clinical and Laboratory Standards Institute's Approved Standards (CLSI). Tube interiors are sterile.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

See comparison studies

b. *Linearity/assay reportable range:*

Not applicable

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Not applicable

d. *Detection limit:*

Not applicable

e. *Analytical specificity:*

Not applicable

f. *Assay cut-off:*

Not applicable

2. Comparison studies:

a. *Method comparison with predicate device:*

Performance characteristics were established in a three-center study. Samples from 2 x 50 apparently healthy adults were tested in pools using the Chiron® **Procleix™** HIV-1/HCV Assay (Site 1), or Roche COBAS AmpliScreen™ HIV-1 Test and Roche COBAS AmpliScreen™ HCV Test (Site 2), respectively.

The samples from known 27 HCV 25 or HIV-1 patients were quantified for HCV using the Bayer VERSANT HCV RNA 3.0 Quantitative Assay (bDNA), or quantified for HIV-1 using the Roche COBAS Amplicor Monitor® Kits (ROCHE) in multiple replicates (volume permitting) (Site 3). All testing was performed within 24 hours of blood collection.

The 2 x 50 samples from apparently healthy patients were tested in 3 pools of 16 and 2 pools of 24 at Sites 1 and 2, respectively, with 2 additional samples at each site tested individually, in accordance with the package inserts. Separate pools were prepared from the samples collected in the Greiner tubes and from the samples collected in the BD tubes. The results for the Greiner tubes were concordant with the results from the BD tubes – the pools and individual samples from the two types of tubes were **non-reactive** for HIV- 1 and HCV RNA.

Qualitative results of the HCV and HIV-1 testing are summarized in Tables 1 and 2, respectively. For the HIV-1 summary, samples with results of "Target Not Detected" (TND) were counted as <LLD.

Samples with results < 300 RNA copies/mL plasma for the Roche Amplicor HIV-1 Monitor Test showed discordant results within a tube type. One example of this is the sample footnoted in the table which had values of 34, 24, and 29 with the BD tube, and 37, 82, and 78 with the Greiner tube. Another sample had values of 294, TND, 26 with the BD tube, and 35, TND, and TND with the Greiner tube.

Table 1: Qualitative HCV bDNA Results on Patients– Individual Samples

		Greiner EDTA K3 Tubes		
		>LLD[a]	<LLD	Total
BD PPT Tubes	>LLD	18	0	18
	<LLD	0	9[c]	9
	Total	18	9	27

[a] LLD = Lower Limit of Detection of the assay (615 IU/ml)

Table 2-4: Qualitative HIV-1 PCR Results on Patients– Individual Samples

		Greiner EDTA K3 Tubes		
		>LLD[a]	<LLD	Total
BD PPT Tubes	>LLD	11	2[c]	13
	<LLD	2[b]	10	12
	Total	13	12	25

[a] LLD = Lower Limit of Detection of the assay (50 RNA copies/ml plasma).
[b] 2 sample had 2 results with the Greiner tube that were > 50, but < 95. Mean Greiner result was 65.5, with %CV = 37.8%; mean BD result was 28.9, with %CV = 18.0%.
[c] 2 samples had 1 result with the BD tube that was >50 (198 and 294), the other 2 results were <50.

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

See comparison studies

4. Clinical cut-off**:**

   Not applicable

5. Expected values/Reference range:

   Not applicable

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.